

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL
May 29, 2003

Gaithersburg Holiday Inn, Walker/Whetstone room, 2 Montgomery Village Avenue, Gaithersburg, MD

9:00 – 5:00	PMA Discussion, Recommendations, and Voting
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9:00 a.m.	Call to Order	Warren K. Laskey, M.D., Acting Chairperson
9:05 – 9:30a.m.	Office of Surveillance and Biometrics Presentation “Diathermy Interactions with Implanted Leads and Implanted Systems with Leads” <i>Marian Kroen, OSB/Issues Management Staff</i>	
9:30 – 10:00 a.m.	*Open Public Session*	
10:00 – 11:00 a.m.	Sponsor Presentation: Cardima, Inc. P020039, Revelation Tx & NavAblator Catheter System	
11:00 – 11:15 a.m.	Questions and Answers	
11:15 – 11:30 a.m.	Break	
11:30 – 12:30 p.m.	FDA Presentation	
12:30 – 12:45 p.m.	Questions and Answers	
12:45 p.m.	Adjourn – Break for Lunch	
1:45 – 2:45 p.m.	Call to Order	
2:45 – 3:45 p.m.	Open Committee Discussion	Warren K. Laskey, M.D.
3:45 – 4:00 p.m.	Break	
4:00 – 5:00 p.m.	*Open Public Session* FDA Comments Sponsor Comments Recommendations & Vote	Warren K. Laskey, M.D.
5:00 p.m.	Adjourn	

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Wood will present the speakers who have requested time for presentation to the Panel. After the

scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Laskey will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.